

Appl. No. 09/402,446
Amdt. Dated October 22, 2004
Reply to Office action of May 3, 2004

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-22 (cancelled).

Claim 23 (currently amended): A method of increasing the serum half-life of an anti-Rh_oD immune globulin comprising:

(a) combining the anti-Rh_oD immune globulin and a non-ionic surface active agent into an immune globulin preparation wherein the concentration of the anti-Rh_oD immune globulin is about 2 weight percent to about 10 weight percent of the preparation and wherein said non-ionic surface active agent is in a concentration sufficient to increase the serum half-life of the immune globulin; and

(b) parenterally administering the anti-Rh_oD immune globulin preparation to an animal in need of the immune globulin.

Claim 24 (cancelled).

Claim 25 (currently amended): A method according to claim 23 24 wherein the anti-Rh_oD immune globulin has an IgG purity of greater than about 95% and a monomeric protein content of greater than about 94%.

Claim 26 (previously presented): A method according to claim 25 wherein the immune globulin preparation is an aqueous formulation.

Claim 27 (cancelled).

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Claim 28 (cancelled).

Claim 29 (cancelled).-

Claim 30 (cancelled).

Claim 31 (previously presented): A method according to claim 23 wherein the non-ionic surface active agent is a sorbitan ester of a fatty acid.

Claim 32 (previously presented): A method according to claim 31 wherein the non-ionic surface active agent is selected from the group consisting of sorbitan monolaurate, sorbitan monopalmitate, sorbitan monostearate, sorbitan tristearate, sorbitan monooleate, and sorbitan trioleate.

Claim 33 (previously presented): A method according to claim 23 wherein the surface active agent is a polyoxyethylene sorbitan ester of a fatty acid.

Claim 34 (previously presented): A method according to claim 33 wherein the non-ionic surface active agent is selected from the group consisting of polyoxyethylene (20) sorbitan monolaurate, polyoxyethylene (4) sorbitan monolaurate, polyoxyethylene (20) sorbitan monopalmitate, polyoxyethylene (20) sorbitan monostearate, polyoxyethylene (4) sorbitan monostearate, polyoxyethylene (20) sorbitan tristearate, polyoxyethylene (20) sorbitan monooleate, polyoxyethylene (5) sorbitan monooleate, and polyoxyethylene (20) sorbitan trioleate.

Claim 35 (previously presented): A method according to claim 23 wherein the non-ionic surface active agent is selected from the group consisting of polyoxyethylene (20) sorbitan monolaurate, polyoxyethylene (4) sorbitan monolaurate, polyoxyethylene (20) sorbitan monopalmitate; polyoxyethylene (20) sorbitan monostearate, polyoxyethylene (4) sorbitan monostearate, polyoxyethylene (20) sorbitan tristearate, polyoxyethylene (20) sorbitan monooleate, polyoxyethylene (5) sorbitan monooleate, and

polyoxyethylene (20) sorbitan trioleate, sorbitan monolaurate, sorbitan monopalmitate, sorbitan monostearate, sorbitan tristearate, sorbitan monooleate, and sorbitan trioleate.

Claim 36 (previously presented): A method according to claim 23 wherein the concentration of the non-ionic surface active agent is about 0.01 weight percent to about 0.5 weight percent.

Claim 37 (previously presented): A method according to claim 23 wherein the immune globulin preparation is a lyophilized preparation that is reconstituted in a physiologically compatible medium prior to administration to the animal.

Claim 38 (currently amended): A method according to claim 23 wherein the immune globulin preparation comprises:

about 3-8% human anti-Rh_oD immune globulin with an IgG purity of greater than 95% and a monomeric protein content of greater than 94%;
sodium chloride at about 0.25% (w/v);
polyoxyethylene sorbitan monooleate at about 0.01% to about 0.5% (w/v); and
L-glycine at about 0.1M.

Claim 39 (previously presented): A method according to claim 23 wherein the non-ionic surface agents is selected from the group consisting of glyceryl monooleate and a polyvinyl alcohol.

Claims 40-56 (cancelled).

Claim 57 (currently amended): A method of increasing the serum half-life of a-an anti-Rh_oD polyclonal immune globulin comprising:

(a) combining the polyclonal anti-Rh_oD immune globulin and a non-ionic surface active agent into an immune globulin preparation, wherein said non-ionic surface active agent is in a concentration sufficient to increase the serum half-life of the polyclonal immune globulin; and

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(b) parenterally administering the anti-Rh_oD immune globulin preparation to an animal in need of the immune globulin.

Claim 58 (cancelled).

Claim 59 (currently amended): A method according to claim 57 58 wherein the anti-Rh_oD immune globulin has an IgG purity of greater than about 95% and a monomeric protein content of greater than about 94%.

Claim 60 (previously presented): A method according to claim 59 wherein the immune globulin preparation is an aqueous formulation.

Claim 61 (cancelled).

Claim 62 (cancelled).

Claim 63 (cancelled).

Claim 64 (currently amended): A method according to claim 57 wherein the concentration of the anti-Rh_oD immune globulin is about 2 weight percent to about 10 weight percent.

Claim 65 (previously presented): A method according to claim 57 wherein the non-ionic surface active agent is a sorbitan ester of a fatty acid.

Claim 66 (previously presented) A method according to claim 65 wherein the non-ionic surface active agent is selected from the group consisting of sorbitan monolaurate, sorbitan monopalmitate, sorbitan monostearate, sorbitan tristearate, sorbitan monooleate, and sorbitan trioleate.

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Claim 67 (previously presented): A method according to claim 65 wherein the non-ionic surface active agent is a polyoxyethylene sorbitan ester of a fatty acid.

Claim 68 (previously amended): A method according to claim 67 wherein the non-ionic surface active agent is selected from the group consisting of polyoxyethylene (20) sorbitan monolaurate, polyoxyethylene (4) sorbitan monolaurate, polyoxyethylene (20) sorbitan monopalmitate, polyoxyethylene (20) sorbitan monostearate, polyoxyethylene (4) sorbitan monostearate, polyoxyethylene (20) sorbitan tristearate, polyoxyethylene (20) sorbitan monooleate, polyoxyethylene (5) sorbitan monooleate, and polyoxyethylene (20) sorbitan trioleate.

Claim 69 (previously presented): A method according to claim 57 wherein the non-ionic surface active agent is selected from the group consisting of polyoxyethylene (20) sorbitan monolaurate, polyoxyethylene (4) sorbitan monolaurate, polyoxyethylene (20) sorbitan monopalmitate; polyoxyethylene (20) sorbitan monostearate, polyoxyethylene (4) sorbitan monostearate, polyoxyethylene (20) sorbitan tristearate, polyoxyethylene (20) sorbitan monooleate, polyoxyethylene (5) sorbitan monooleate, and polyoxyethylene (20) sorbitan trioleate, sorbitan monolaurate, sorbitan monopalmitate, sorbitan monostearate, sorbitan tristearate, sorbitan monooleate, and sorbitan trioleate.

Claim 70 (previously presented): A method according to claim 57 wherein the concentration of the non-ionic surface active agent is about 0.01 weight percent to about 0.5 weight percent.

Claim 71 (currently amended): A method according to claim 57 wherein the immune globulin preparation is a lyophilized preparation that is reconstituted in a physiologically compatible medium prior to administration to the animal.

Claim 72 (currently amended): A method according to claim 57 wherein the immune globulin preparation comprises:

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about 3-8% human anti-Rh_oD immune globulin with an IgG purity of greater than 95% and a monomeric protein content of greater than 94%;
sodium chloride at about 0.25% (w/v);
polyoxyethylene sorbitan monooleate at about 0.01% to about 0.5% (w/v); and
L-glycine at about 0.1M.

Claim 73 (previously presented): A method according to claim 57 wherein the non-ionic surface agent is selected from the group consisting of glyceryl monooleate; and a polyvinyl alcohol.

Claim 74 (new): An aqueous immune globulin preparation for parenteral administration comprising an anti-Rh_oD immune globulin and at least one non-ionic surface active agent.

Claim 75 (new): An aqueous immune globulin preparation according to claim 74 wherein the non-ionic surface active agent is a sorbitan ester of a fatty acid.

Claim 76 (new): An aqueous immune globulin preparation according to claim 74 wherein the non-ionic surface active agent is a polyoxyethylene sorbitan ester of a fatty acid.

Claim 77 (new): An aqueous immune globulin preparation according to claim 74 wherein the concentration of the non-ionic surface active agent is about 0.01 weight percent to about 0.5 weight percent.

Claim 78 (new): An aqueous immune globulin preparation according to claim 74 wherein the anti-Rh_oD immune globulin has an IgG purity of greater than about 95% and a monomeric protein content of greater than about 94%.

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Claim 79 (new): An aqueous immune globulin preparation according to claim 74 wherein the concentration of the anti-Rh_oD immune globulin is about 2 weight percent to about 10 weight percent.

Claim 80 (new): An aqueous immune globulin preparation according to claim 74 wherein the anti-RhoD antibodies are polyclonal.